## REMARKS

In the aforesaid Office Action, the Examiner rejected claims 1-33 on a variety of bases, but has indicated that claims 21-27 would be allowable if rewritten to overcome the rejections under 35 U.S.C. §112(2).

### Response Rejection Under 35 U.S.C §102

In the aforesaid Office Action, the Examiner, rejected Claims 1-6, 11, 12, 28 and 31-33 as being anticipated by Schulz et al. (US Patent No. 5,246,787) and claims 1-5, 7-20, 28, 29 and 31-33 as being anticipated by Aita (U.S. 5,472,795). Applicants have amended the claims to focus on an intracorporeal device or substrate for such a device having protective coating with an outer coating component that is water-swellable or self sealing. Neither cited reference teach this feature and therefore cannot anticipate applicants' claims.

### Response To Rejection Under 35 U.S.C. §103

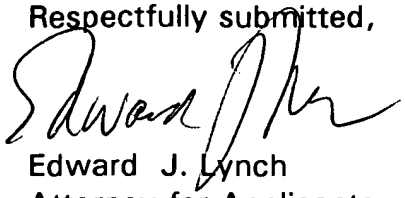
In the Office Action the Examiner rejected Claims 7, 8, and 13-16 under 35 U.S.C. §103 as being unpatentable over Schulz et al. (US 5,246,787) in view of Armini et al. (US 5,674,293) and rejected Claims 19, 20, 29, and 30 as being unpatentable over Schulz et al. (US 5,246,787) in view of Davidas (US 4,326,305).

Applicants respectfully submit that Claims 7, 8, 13-16 are patentable over Schulz et al. in view of Armini et al. Schulz et al. does not meet the requirements of the rejected claims, e.g. does not suggest a water swellable, ceramic coating layer less than 100 nm thick and the secondary reference Armini et al. fails to

make up for this deficiency. Other deficiencies are apparent. Claims 29 and 30 are distinguishable for essentially the same reasons.

The above amendments overcomes each and every rejection and objection set forth in the Office Action mailed on September 26, 2001, and respectfully requests reconsideration and the allowance of the claims. Marked up copies of the above amendments are attached.

Respectfully submitted,



Edward J. Lynch
Attorney for Applicants
Registration No. 24,422

COUDERT BROTHERS LLP
600 Beach Street, Third Floor
San Francisco, CA 94109
**Direct Dial: (415) 351-5708**
Telephone: (415) 409-2900
Facsimile: (415) 409-7400

## MARKED-UP COPY OF AMENDMENTS TO SPECIFICATION

**Replace the paragraph starting on page 3, line 7, and continuing to page 4, line 5, with the following paragraph:**

----The present invention is directed to a multilayered protective coating formed of ceramic materials. The coating comprising an inner component or module which has at least <u>one, preferably</u> two layers of ceramic materials such as zirconia, titania and alumina [wherein] <u>therein</u>. The coating further comprises an outer component or module disposed on the inner component formed of <u>a water swellable</u> ceramic material capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment, e.g. water based fluids such as blood[, so as to be swellable in such an environment]. Preferably, ceramic material for the outer component or module comprises an aluminum, zirconium or hafnium compound, more preferably, a nitride of such materials. The presently most preferred swellable component is a hydrate or hydroxide compound such as aluminum hydroxide, aluminum hydrate, and mixtures thereof. The inner component is preferably a series of bilayers comprising zirconia and titania and zirconia and alumina. The thickness of the coating layers range from about 1 to about 100 nanometers, preferably about 1 to 50 nanometers. The overall coating thickness can range up to several microns.

**IN THE CLAIMS**

**Please amend claims 1 -19, claims 21 – 31 and claim 33 to read as follows:**

1. (Amended) An intracorporeal device having [A] a protective coating [for a intracorporeal substrate] on a surface thereof, comprising:

a. an inner coating component having at least one [inner] layer formed of ceramic material on the surface of the device; and

b. an outer coating component having at least one layer less than 100 nm thick formed of a water swellable ceramic material on the inner coating component.

2. (Twice Amended) The [protective coating] intracorporeal device of Claim 1 wherein the [at least one] inner [layer] coating component includes a plurality of bilayers.

3. (Twice Amended) The [protective coating] intracorporeal device of Claim [2] 1 wherein the ceramic material [for] of the at least one layer of the inner coating component [layer] is selected from the group consisting of zirconia, titania and alumina.

4. (Amended) The [protective coating] intracorporeal device of Claim 1 wherein the water swellable ceramic material forms a hydrate or hydroxide in the presence of an oxygen containing environment.

5. (Twice Amended) The [protective coating] intracorporeal device of Claim [2] 4 wherein the water swellable ceramic material is selected from the

group consisting of alumina, zirconia[.] , and hafnia containing [components] ceramic materials.

6. (Twice Amended) The [protective coating] intracorporeal device of Claim [5] wherein the water swellable ceramic material is a nitride [of material selected from the group consisting of alumina, zirconia and hafnia].

7. (Amended) The [protective coating] intracorporeal device of Claim 1 wherein the individual layers of the inner coating component are about one to about 100 nanometers thick.

8. (Amended) The [protective coating] intracorporeal device of Claim 1 wherein the individual layers of the inner coating are about one to about 50 nanometers thick.

9. (Amended) The [protective coating] intracorporeal device of Claim 1 [having] wherein the inner coating component has at least one bilayer [of] with zirconia in one layer and alumina in the other layer.

10. (Amended) The [protective coating] intracorporeal device of Claim 1 [having] wherein the inner coating component has at least one bilayer [of] with zirconia in one layer and titania in the other layer.

11. (Amended) The [coating] intracorporeal device of Claim 4 wherein the hydrate or hydroxide compound is selected from the group consisting of aluminum hydroxide, aluminum hydrate, and mixtures thereof.

12. (Amended) The [coating] intracorporeal device of Claim 1 wherein the inner and outer coating components have [having] a thickness of up to about a micron.

13. (Amended) The [coating] intracorporeal device of Claim 5 wherein the inner and outer coating components have [has] a thickness in a range from about 1 to 50 nanometers.

14. (Amended) The [coating] intracorporeal device of Claim 1 wherein the at least one layer includes a plurality of nano-scale ceramic layers independently forming a hardness-imparting ceramic [module] coating component and a toughness-imparting ceramic [module] coating component.

15. (Amended) The [coating] intracorporeal device of Claim [1] 14 wherein [the] each of the hardness-imparting and the toughness-imparting [modules] coating components has a thickness independently ranging from about 1 to about 100 nm.

16. (Amended) The [coating] intracorporeal device of Claim 1 wherein the outer [layer] coating component has a thickness in the range from about 1 to about 100 nm.

17. (Amended) A nanostructure protective coating for a substrate, the coating comprising a plurality of nano-scale ceramic layers including an inner coating component secured to the substrate having at least one bilayer with one layer formed of [different] material selected from the group consisting of zirconia, titania, alumina, and aluminum nitride and another layer formed of a different

material selected from the same group of materials and a self sealing outer coating component.

18. (Amended) A nanostructure protective coating for a substrate, the coating comprising an [outermost] outer coating [layer] component comprising a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment and an [innermost] inner coating [layer] component secured to the substrate comprising a bilayer of ceramic materials.

19. (Amended) The coating of Claim 18 wherein the [outermost layer] outer coating component comprises an aluminum compound.

21. (Amended) An intracorporeal implant, comprising:

a substrate selected from the group consisting of metals, polymers, and a combination thereof; and [the substrate having]

a protective coating thereon[, the protective coating comprising:] having a plurality of [modules] coating components comprising

a first [module] coating component having [comprising] a [number (m)] plurality of bilayers [comprising] wherein each layer is formed of a material selected from the group consisting of zirconia and alumina [wherein (m ) is a number greater than 1];

a second [module] coating component disposed on the first [module] coating component having [comprising] a [number (n)] plurality of bilayers [comprising] with each layer formed of a material selected from the group consisting of zirconia and titania [wherein (n) is a number greater than 1]; and

a third [module] coating component disposed on the second [module] coating component [comprising a third-module] formed of a compound which has microcrystallinity and which is capable of forming a hydrate or hydroxide [compound] upon contact with an oxygen containing environment.

22. (Amended) The implant of Claim 21 wherein the [third module-] compound [comprises] is an aluminum compound.

23. (Amended) The implant of Claim 21 wherein the [third module-] compound [comprises] is aluminum nitride.

24. (Amended) The implant of Claim 21 wherein the [hydrate or hydroxide] compound is selected from the group consisting of aluminum hydroxide, aluminum hydrate, and mixtures thereof.

25. (Amended) The implant of Claim 21 wherein the coating thickness is in a range from about 1 to about 100 nanometers.

26. (Amended) The implant of Claim 21 wherein the coating thickness is in a range from about 1 to 50 nanometers.

27. (Amended) An intracorporeal implant, comprising:

a substrate selected from the group consisting of metals, polymers, and a combination thereof having a protective coating thereon, comprising:

a plurality of nano-scale ceramic layers with each layer formed of one or more compounds selected from the group consisting of zirconia, titania, alumina, and aluminum nitride.

28. (Amended) An intracorporeal implant, comprising a substrate selected from the group consisting of metals, polymers, and a combination thereof and having a protective coating thereon which has [an outermost] a self sealing outer coating [layer] component having nano-crystallinity and comprising a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment.

29. (Amended) The implant of Claim 28 wherein the [outermost] outer coating [layer] component comprises an aluminum compound.

31. (Amended) The protective coating of Claim 1 wherein the outer [layer] coating component is formed at least in part of a [non-crystalline] nano-crystalline water swellable material.

33. (Amended) The implant of Claim 28 wherein the coating further [including] includes a plurality of [non] nano-scale ceramic layers independently forming a hardness-imparting [ceramic module] coating component and a toughness-imparting [module] coating component.